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Re-evaluation Note REV2017-15

Re-evaluation Project Plan for Isoxaflutole

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Background

In Canada, isoxaflutole is under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). PMRA re-evaluates registered pesticides to determine whether the use of these products continues to be acceptable in terms of value, human health and the environment according to current standards.

Isoxaflutole is a broad spectrum herbicide. It is registered for use in field corn and isoxaflutole-tolerant soybean in Eastern Canada and British Colombia, and for use in seed corn in Eastern Canada, for the control of broadleaf and annual grass weeds. As of 4 May 2017, five products containing isoxaflutole are registered in Canada, including one technical grade active ingredient and four end-use products.

Under the authority of section 16 of the *Pest Control Products Act*, the registrant of isoxaflutole in Canada was notified of the initiation of this re-evaluation. Following this, the registrant indicated support of all uses included on the labels of end use products in Canada.

The re-evaluation project plan below outlines the timeline, the anticipated areas of focus for the risk assessments, and the data requirements for the re-evaluation of isoxaflutole.

Re-evaluation Project Plan

Anticipated Re-evaluation Timeline

The re-evaluation of isoxaflutole is defined as a Category 1 as described in Regulatory Directive DIR2016-04, *Management of Pesticides Re-evaluation Policy*, which was adopted on 1 December 2016. However, because this re-evaluation was initiated prior to the publication of DIR2016-04, the proposed re-evaluation decision for isoxaflutole is anticipated to be published for consultation by May 2019. The re-evaluation timeline may be updated if, during the risk assessment, PMRA identifies additional areas of focus that should be considered.

Human Health Risk Assessment

New assessments will be conducted for toxicology and postapplication exposure. Existing assessments with minor updates are considered to be adequate to support the re-evaluation of isoxaflutole for the other aspects of human health assessment.

Environmental Risk Assessment

New assessments will be conducted for environmental fate, water modelling and environmental exposure.

Value

The value of isoxaflutole will be considered. The viability of alternatives will be examined for certain uses if risks of concern requiring mitigation are identified.

Data Requirements

PMRA has identified the need for the technical registrant to provide data for isoxaflutole related to toxicology and environmental toxicology. Relevant data/studies have been requested from the technical registrant. A summary of the data call-in is found PMRA's Public Registry, found online at http://www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#ppid. For a list of data categories that have been required, see Appendix I. In addition, information regarding the registered use pattern has been requested from the registrants, to inform the risk assessments.

Additional Information

PMRA documents can be found in the Pesticides and Pest Management section of Health Canada's website at healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service:

Phone:	1-800-267-6315	within Canada or
	1-613-736-3799	outside Canada (long distance charges apply)
Fax:	1-613-736-3798	
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Appendix I Data Required Under Subsection 19(1) of the *Pest Control Products Act* for the Re-evaluation of Isoxaflutole

I Toxicology Data

4.4	Long-term Studies - TGAI
4.5.1	Multigeneration Reproduction (rodent)
4.5.8	Other Genotoxicity Studies
4.5.9	Metabolism/Toxicokinetics in Mammals (laboratory animals)
4.5.12	Acute Neurotoxicity (rat)
4.5.13	90-day Neurotoxicity (rat)
4.5.14	Developmental Neurotoxicity
4.5.15	Immunotoxicity
4.8	Other Studies /Data / Reports

II Environmental Toxicology Data

9.2.3.1	Acute Toxicity (Earthworms)
9.2.4.3	Hive Study (including Brood)
9.2.8	Laboratory studies on Non-Target Terrestrial Invertebrates
9.3.2	*Daphnia* sp. Acute
9.3.4	Laboratory Studies with Other Species (Non-Target Freshwater Invertebrates)
9.4.2	Acute (Crustacean)
9.5.2.4	Marine/Estuarine Fish (Acute Studies)
9.5.3.1	Fish, Early Life Cycle Toxicity Test
9.6.2.4	Dietary (LC_{50}) Bobwhite Quail
9.6.3.1	Avian Reproduction Bobwhite Quail
9.8.2	Fresh Water Algae
9.8.5	Aquatic Vascular Plants